

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 9, 2021

LARRY WOLFORD,

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PUBLISHED

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Petitioner,

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No. 17-451V

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v.

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Special Master Nora Beth Dorsey

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Ruling on Entitlement; Causation-in-Fact;

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Influenza (“Flu”) Vaccine; Shoulder Injury

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Related to Vaccine Administration

Respondent.

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(“SIRVA”).

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Isaiah Richard Kalinowski, Muller Brazil, LLP, Dresher, PA, for petitioner.

Kyle Edward Pozza, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

On March 29, 2017, Larry Wolford (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. § 300aa-10 *et seq.* (2012).² Petitioner alleges that he suffered a right shoulder injury as the result of an influenza (“flu”) vaccination administered on November 11, 2015. Petition at 1-3 (ECF No. 1).

¹ Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has provided preponderant evidence that the flu vaccine caused his right shoulder injury, which satisfies his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

I. PROCEDURAL HISTORY

Petitioner filed his petition on March 29, 2017, alleging that he sustained a right shoulder injury caused by a flu vaccine administered on November 11, 2015. Petition at 1-3. The early procedural history from March 2017 through June 2019 was set forth in the undersigned's Fact Ruling and will not be repeated here. Fact Ruling dated July 8, 2019, at 2-3 (ECF No. 56).

Thereafter, this case was removed from the Special Processing Unit ("SPU"). Petitioner filed additional documentation between August and December 2019. Pet. Exs. 30-32. On March 20, 2020, petitioner filed an expert report from Dr. Tony Korman. Pet. Ex. 33. Respondent filed an expert report from Dr. Paul Cagle on July 27, 2020. Resp. Ex. A.

On September 22, 2020, petitioner filed a memorandum in support of petitioner's entitlement to compensation. Memorandum in Support of Petitioner's Entitlement to Compensation ("Pet. Memo."), filed Sept. 22, 2020 (ECF No. 75). Respondent filed his response on November 13, 2020. Respondent's Response to Pet. Motion for Ruling on the Record ("Resp. Response"), filed Nov. 13, 2020 (ECF No. 78). Petitioner filed a reply on December 1, 2020. Reply Memo. in Support of Pet. Entitlement to Compensation ("Pet. Reply"), filed Dec. 1, 2020 (ECF No. 79).

This matter is now ripe for adjudication.

II. FACTUAL HISTORY

A. Pre-Vaccination Medical History

Petitioner's pre-vaccination medical history is significant for non-insulin dependent diabetes mellitus, diabetic neuropathy, weakness, fatigue, numbness in hands and legs, backache, multiple joint pains, gastroesophageal reflux disease, depression, and osteoarthritis. Pet. Ex. 4 at 4-5, 7, 16, 26, 28.

On November 9, 2005, while working in the coal mines as a fine clean coal operator, petitioner injured his lower back when lifting 55 gallon wood barrels. Pet. Ex. 31 at 9-10, 19, 59. In his worker's compensation claim,³ he explained that by November 14, the pain was so severe he sought medical treatment. Id. at 10. At the time he filed his claim on April 27, 2006, he was undergoing physical therapy, taking pain medications, and unable to return to work. Id. at 10-11.

³ In his 2006 workers compensation claim, petitioner indicated he filed another worker's compensation claim in 1985 after cutting his leg with a chainsaw. Pet. Ex. 31 at 11.

According to petitioner's workers compensation file and social security records, petitioner's complaints of multiple joint pain began in 2005. Pet. Ex. 31 at 141; Pet. Ex. 32 at 167. Petitioner was diagnosed with osteoarthritis.⁴ Id. In physical therapy records from 2005, petitioner reported a history of osteoarthritis in right hip and knee. Pet. Ex. 32 at 110. No records indicate that petitioner had right shoulder pain prior to vaccination.

B. Post-Vaccination Medical History

The Fact Ruling set forth a summary of petitioner's medical records, affidavits, and hearing testimony relative to onset of his right shoulder injury. See Fact Ruling at 3-8. Only the relevant portions will be repeated here. In the Fact Ruling, the undersigned found the onset of petitioner's right shoulder injury was within 48 hours of vaccination. Id. at 13.

On November 11, 2015, at fifty-three years old, petitioner was seen by his primary care physician, Dr. Patel. Pet. Ex. 4 at 34. Current medications included Ultram,⁵ Cymbalta,⁶ and Neurontin.⁷ Id. at 34-35. Chief complaints were diabetes mellitus and hypercholesterolemia. Id. at 34. Petitioner also complained of backache and itching and rash on his right arm. Id. He came for a check up on his blood sugar and wanted a flu vaccine. Id. Physical examination by Dr. Patel revealed tenderness in lower back, dermatitis on right arm, and normal range of motion.

⁴ Osteoarthritis is "a noninflammatory degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane," and "[i]t is accompanied by pain." Osteoarthritis, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=35780> (last visited June 23, 2021).

⁵ Ultram is a trademark for tramadol hydrochloride, "an opioid analgesic used for the treatment of moderate to moderately severe pain following surgical procedures and oral surgery." Ultram, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=51748> (last visited June 23, 2021); Tramadol Hydrochloride, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=50542> (last visited June 23, 2021).

⁶ Cymbalta, a trademark for duloxetine hydrochloride, is used for "the relief of pain in diabetic neuropathy." Cymbalta, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=12214> (last visited June 23, 2021); Duloxetine Hydrochloride, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15011> (last visited June 23, 2021).

⁷ Neurontin, or gabapentin, is used to treat and manage postherpetic neuralgia, or "persistent burning pain and hyperesthesia along the distribution of a cutaneous nerve." Neurontin, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=33803> (last visited June 23, 2021); Gabapentin, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=19523> (last visited June 23, 2021); Postherpetic Neuralgia, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92490> (last visited June 23, 2021).

Id. At this visit, Ms. Lynette Gibson administered a flu vaccine in petitioner's right deltoid. Pet. Ex. 10 at 1. Dr. Patel documented, "Flu Vaccine given. No reaction noted." Pet. Ex. 4 at 35.

At the fact hearing, petitioner testified that when the vaccine was administered, the nurse "said she felt it tighten up on [him], so [he did not] know where she did or what, but she said she felt it tighten up on [him]." Tr. 17. He explained that "when she pulled the needle out, she said it tightened up on her . . . she felt it jerk, the muscle tightened up and everything." Tr. 109-10. Ms. Wolford testified that "when [the nurse] gave [petitioner] his shot she just kind of—I guess laughed a little bit and said he'd probably get sore because [she] felt it jerk." Tr. 157-58, 199. Ms. Wolford testified that she was present during the entire visit with Dr. Patel on November 11, 2015 when petitioner received his flu shot and that she also received a flu shot during this visit. Tr. 157.

Petitioner testified that he began experiencing aching and stiffness the evening of the vaccination. Tr. 19. His shoulder pain disturbed his sleep and woke him up at night beginning the first night following the vaccination. Tr. 35. He had to start driving with one hand "[r]ight after the vaccine." Tr. 36. He explained that a day or two later he developed a stabbing pain. Tr. 26.

Ms. Wolford testified that after they got home, petitioner complained of his shoulder being "sore, a dull, aching sore," but they thought it was normal. Tr. 158. She testified that she did not call Dr. Patel's office that day about petitioner's pain because the nurse "said it was going to get sore, so he just thought it would be normal." Tr. 201; see also Tr. 159. She explained, however, the soreness did not go away but worsened. Tr. 158-59. The day after vaccination, "[petitioner] just all of a sudden would be hollering, ouch, and grabbing to his arm." Tr. 159.

Petitioner explained that he made a "sleeve," or sling, out of a compression sock that, when worn as a sleeve, warmed his arm and reduced his discomfort. Tr. 19-20, 26, 31-33. His pain also got better with Tylenol, ibuprofen, and Icy Hot. Tr. 118-19. Ms. Wolford also testified to these facts. Tr. 159.

Ms. Wolford testified that as time went on in November and December 2015, petitioner would "treat it for a while and then it would go away, and it'd like just come back [She] remember[ed] him propping it up on, like, a pillow to ease the pain." Tr. 160. They also did this with other items like quilts. Id. Ms. Wolford recalled seeing petitioner "trying to comb his hair, and he couldn't get his arm up over his head to comb his hair, like he was having trouble moving his arm." Tr. 161. She could not recall when she observed this but stated that it was before April 2016 and possibly before February 2016. Tr. 161, 173-74.

Ms. Wolford testified that she was not sure when she first called Dr. Patel's office, but believed it was sometime around mid-November or Thanksgiving. Tr. 162-63, 202. She testified that she was told that Dr. Patel "was out of the country at that time" and that he would

be gone for a month.⁸ Tr. 163, 205. Petitioner's wife testified that petitioner did not see another doctor in the practice because Dr. Patel had "been his doctor for years. He's the only one he sees" and they planned to "wait for him to come back." Tr. 163-64. She testified that she did not initially look for other doctors because petitioner was treating himself and the pain was coming and going. Tr. 164.

Ms. Wolford testified that eventually she started calling other doctors in the area that she identified by going through a phone book. Tr. 164. She could not recall the names of the offices she called but stated that there were "a few" and that "they couldn't get him in because . . . they wanted a referral or where it was the holidays and stuff, they wanted it two or three months down the road." Tr. 185. She contacted the office of chiropractor Dr. Jarrod Thacker and was told that he could see petitioner. Tr. 165. She could not recall the interval between when she called Dr. Thacker's office and when petitioner was first seen by Dr. Thacker, but said that "it wasn't that long. Probably a couple of days . . . they got him in quick." Id.

Petitioner presented to Dr. Thacker on February 16, 2016 with "severe upper thoracic/right shoulder/arm/elbow thumb pain" that "started after receiving a flu shot in November 2015." Pet. Ex. 5 at 3. Petitioner noted onset as "acute, one week after flu shot was administered."⁹ Id. Petitioner reported "pain daily 4/5 times a day [and] made worse with certain movements. Pain ranges from 2-8/10 on a pain scale." Id. Pain was described as "achy, burning, dull, sharp, stiff, throbbing," and moderate. Id. Petitioner further reported numbness in right hand, severe spasms in right cervical paraspinal and right trapezius, right upper extremity weakness, and decreased cervical motion. Id. He indicated he was only able to lift 25 pounds and his sleep was affected. Id. On physical examination, Dr. Thacker wrote petitioner "presents with severe [guarding] of the neck and right shoulder." Id. Petitioner had decreased range of motion. Id. Dr. Thacker treated petitioner to relieve pain, decrease inflammation, and to improve function, strength, and range of motion. Id. at 4. Petitioner was given shoulder exercises and stretches for impingement syndrome. Id.

Petitioner returned to Dr. Thacker numerous times from February to November 2016. Pet. Ex. 5 at 6-56; Pet. Ex. 6 at 2-22, 24-32. During the February 24, 2016 visit, Dr. Thacker wrote "[a] MRI consult was discussed with [petitioner] because progression not optimal.

⁸ In a later record, Dr. Patel included a note stating, "[petitioner] states he came to see me in Nov[ember] 2015, I [saw] him on 11-11-15 but he came again to see me and I was out of town and he [saw] Jerry Thacker for right shoulder pain and received physical therapy." Pet. Ex. 7 at 5; see also Pet. Ex. 9 at 5 (handwritten version of similar note).

⁹ Petitioner testified that the notation stating the onset was one week after the flu shot is not accurate. Tr. 49, 127-28, 206-07.

[Petitioner] would need to visit PCP (Dr. D Patel) to obtain order form [for] R shoulder MRI.”¹⁰ Pet. Ex. 5 at 13.

On February 29, 2016, petitioner returned to Dr. Patel’s office¹¹ with a chief complaint of diabetes mellitus and hypercholesterolemia. Pet. Ex. 4 at 36. Under review of systems, petitioner complained of neck pain and numbness in right arm and reported seeing a chiropractor. Id. Physical examination revealed tenderness in back of neck with painful neck movements, no stiffness in neck, and normal range of motion. Id. Assessment included “neck pain with probable degenerative disc disease c spine,” “cervical radicular syndrome right side,” and osteoarthritis. Id. at 37. Petitioner was advised to have an MRI of his cervical spine done.¹² Id.

An MRI of petitioner’s right shoulder was conducted on March 1, 2016. Pet. Ex. 3 at 2. Diagnosis was listed as shoulder pain and soreness after flu shot. Id. The impression was “[s]omewhat inferiorly projecting acromion process with mild increased signal intensity changes in the subacromial bursa could represent impingement syndrome^[13] or from bursitis.^[14] Study otherwise is negative for rotator cuff tear.” Id.

Dr. Thacker’s examinations in March and April 2016 “show[ed] minimal to no improvement in [petitioner’s] subjective or objective complaints/findings.” Pet. Ex. 5 at 24, 48. Dr. Thacker discussed a referral to an orthopedist for an injection. Id.

¹⁰ Dr. Thacker’s additional patient notes regarding petitioner’s shoulder MRI are as follows:

4-7-16: Appointment with patient PCP was set up for 4-13-16 to obtain order for right shoulder MRI. Patient progress not showing expected results. Patient still suffering from severe pain when certain motions are sought (Mostly overhead/abduction/adduction to R shoulder).

4/14/16: Patient had follow up visit with PCP to get a MRI on R shoulder.

4/28/16: Patient was referred to orthopedist for consultation of cortisone injection into right shoulder. Injection was administered by Dr. Varney at PMC.

Pet. Ex. 5 at 2.

¹¹ It is not clear from the record who petitioner saw during this visit.

¹² No records were provided indicating petitioner received a cervical spine MRI. Based on the medical records, it appears petitioner received only a right shoulder MRI.

¹³ Impingement syndrome results from “mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff.” Impingement Syndrome, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=110796> (last visited July 6, 2021).

¹⁴ Bursitis is “inflammation of a bursa.” Bursitis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=7315> (last visited July 6, 2021).

Petitioner returned to Dr. Patel's office¹⁵ on April 11, 2016. Pet. Ex. 4 at 38. Petitioner complained of "right shoulder pain with restricted shoulder movements" as well as multiple joint pain. Id. Physical examination revealed right shoulder tenderness with marked restricted movements and normal range of motion. Id. Assessment included "right shoulder pain etiology to be determined." Id. at 39. Under plan, the record indicates "[a]dvised mri of the right shoulder and [petitioner] is being followed by Dr. [] Thacker." Id. Petitioner was instructed to continue physical therapy. Id.

On April 18, 2016, petitioner saw orthopedist Dr. Jamie Varney at Pikeville Medical Center complaining of right shoulder pain. Pet. Ex. 2 at 3, 7. Petitioner stated "the symptoms have been chronic non-traumatic," occur intermittently, and "began . . . after flu shot." Id. at 3. He described the pain as "piercing" and reported additional pain in his right thumb. Id. at 3, 12. He indicated his "symptoms are aggravated by daily activities and reaching overhead," but are "relieved by physical therapy." Id. At the time of the visit, petitioner reported his symptoms were moderate and his pain was a 2/10. Id. at 3, 11. In a handwritten orthopedic information sheet completed on April 18, 2016,¹⁶ petitioner related his injury back to the flu vaccine received on November 11, 2015 and listed his reason for visit as "pain in right shoulder [and] numbness in thumb." Id. at 11. For when his symptoms started, he wrote "same night got sore." Id. He also described the pain as stabbing and noted it "randomly" goes from 2/10 to 8/10. Id.

Physical examination revealed positive signs on Hawkins and Neer's tests and the cross body test for shoulder joint pathology. Pet. Ex. 2 at 5. Range of motion in petitioner's left shoulder was normal, but there was "pain in impingement arc" noted with regard to petitioner's right shoulder. Id. at 6. Elbow and wrist range of motion in both extremities was normal. Id. Upper extremity strength was normal except for "mild decreased right supraspinatus due to pain." Id. Neurovascular upper extremity examination was normal, although petitioner reported "some decreased sensation on the inner aspect of his thumb." Id. Assessment was impingement syndrome and bursitis of right shoulder. Id. Petitioner received a cortisone injection in the subacromial space in his right shoulder. Id. Dr. Varney stated, "it is unlikely that the flu shot actually caused any damage to his shoulder. MRIs . . . show[] chronic tendinopathy of supraspinatus with some tendinitis and bursitis. Also has a downward sloping acromion that causes rotator cuff impingement. Previous injection may have [] caused some inflammation of his underlying problems."¹⁷ Id. at 7. Petitioner was advised to continue home exercises and physical therapy and ice and take anti-inflammatories as needed. Id.

On August 16, 2016, petitioner returned to Dr. Patel for diabetes mellitus and hypercholesterolemia. Pet. Ex. 7 at 2. Petitioner did not complain of shoulder pain at this visit. See id. Physical examination revealed normal range of motion. Id.

¹⁵ Again, it is not clear from the record who petitioner saw during this visit.

¹⁶ Petitioner and his wife both testified that the handwriting on the form belongs to petitioner's wife. Tr. 73, 175.

¹⁷ Dr. Varney does not define "previous injection." It appears, however, based on the context of the note, that Dr. Varney was referring to the flu vaccination.

On July 21, 2016, petitioner saw Dr. Thacker who noted petitioner “re-injured right shoulder after hanging drywall for 4 hours [on] 7/18/16.” Pet. Ex. 6 at 17.

Petitioner saw Dr. Patel on October 4, 2016, complaining of “rash on the arm with itching backache, numbness in legs. Came for check up on blood sugar. Cough, chest congestion.” Pet. Ex. 7 at 4. On physical examination, range of motion was normal. Id. Dr. Patel noted petitioner saw Dr. Thacker for right shoulder pain and received physical therapy. Id. at 5.

Petitioner complained of diabetes mellitus, hypercholesterolemia, multiple joint pain, numbness in legs, and a cough during a visit to Dr. Patel on December 7, 2016. Pet. Ex. 7 at 6. Petitioner did not complain of right shoulder pain during this visit. See id. Range of motion was normal on physical examination. Id.

Petitioner saw Dr. Patel next on March 9, 2017. Pet. Ex. 9 at 1-2. No complaints of right shoulder pain were noted. See id. Physical examination revealed normal range of motion. Id. at 1. “Right elbow region pain” and “normal range of motion” were noted in petitioner’s next visit to Dr. Patel on June 14, 2017. Id. at 3-4.

No additional medical records were provided.

III. EXPERT REPORTS

A. Petitioner’s Expert, Dr. Jeffrey Boyd

1. Background and Qualifications

Dr. Boyd is a practicing diagnostic radiologist specializing in musculoskeletal radiology. Pet. Ex. 13 at 1. He is board certified in diagnostic radiology. Id. Dr. Boyd received his B.A. in Biochemistry in 2001 and his M.D. in 2005 from the University of Mississippi. Pet. Ex. 14 at 1. Thereafter, he completed an internship in internal medicine, residency in diagnostic radiology, and a fellowship in musculoskeletal radiology. Id. He holds licenses in Kentucky, Indiana, Mississippi, Tennessee, and Arkansas. Id.

2. Opinion

Dr. Boyd opined that more likely than not petitioner’s November 11, 2015 flu vaccination caused petitioner to experience a shoulder injury related to vaccine administration (“SIRVA”), which he continues to suffer from. Pet. Ex. 13 at 8.

For support that a flu vaccine can cause a SIRVA, Dr. Boyd cited Atanasoff et al.¹⁸ Pet. Ex. 13 at 5. In Atanasoff et al., the authors identified thirteen cases filed in the database of claims submitted to the Vaccine Program between 2006 to 2010 where “vaccine administration led to significant shoulder pain and dysfunction.” Pet. Ex. 15 at 1-2. Based on their

¹⁸ S. Atanasoff et al., Shoulder Injury Related to Vaccine Administration (SIRVA), 28 Vaccine 8049 (2010).

investigation, the authors' proposed mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Id. at 1. "[T]he rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. The authors noted that some of their MRI findings "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation. Other findings such as fluid collections, localized tendon inflammation, and bursitis are more consistent with the vaccine needle over-penetration mechanism." Id. at 3-4.

Dr. Boyd agreed with the March 1, 2016 right shoulder MRI findings and opined that the findings are consistent with a SIRVA injury. Pet. Ex. 13 at 3, 6. He acknowledged that petitioner's findings of mild tendinopathy in his supraspinatus and infraspinatus tendons, mild degenerative changes in his acromioclavicular joint, and lateral downsloping of his acromial process are consistent with normal aging and a labor-intensive career. Id. at 6. Although "arthrosis of the acromioclavicular joint and a lateral downsloping acromion can predispose [] subacromial impingement and inflammation in the bursa," Dr. Boyd opined that it did not in petitioner's case because petitioner was asymptomatic prior to his flu vaccination. Id. at 6-7. Petitioner's MRI showed inflammation of the subacromial/subdeltoid bursa, which Dr. Boyd believed was most likely the source of petitioner symptoms. Id. at 7. He found "no evidence of any other internal derangement of the shoulder to explain [petitioner's] symptoms." Id. at 3. Knowing that petitioner received a vaccine in the right shoulder and that he was asymptomatic prior to vaccination, Dr. Boyd opined that "SIRVA would have to be included as a leading differential consideration for the source of his bursal inflammation." Id.

Dr. Boyd opined that the placement of injection "may likely" have affected petitioner. Pet. Ex. 13 at 7. He cited to the administering nurse's note that documented a "jerk" upon administration and that fact that she warned petitioner of a likelihood of soreness due to the abnormality in administration. Id.

With regard to onset, Dr. Boyd opined that petitioner consistently attributed the onset of his systems to his November 2015 flu vaccination. Pet. Ex. 13 at 7. Such a timeframe is consistent with the SIRVA medical literature. Id. at 7-8. Dr. Boyd found petitioner's initial pain due to direct needle trauma and petitioner's worsening pain due to persistent immune-mediated inflammatory response. Id. at 8.

Petitioner's injury is further consistent with a SIRVA diagnosis because he suffered from pain and limited or painful range of motion in his right shoulder. Pet. Ex. 13 at 7. He opined that petitioner's reduced range of motion is consistent with subacromial/subdeltoid bursitis, which can occur after a SIRVA, but not with a radiculopathy. Id. at 8.

Dr. Boyd found no evidence to support a neurologic etiology. Pet. Ex. 13 at 8. Nor did he find any evidence of another condition to explain petitioner's pain or loss of range of motion in his shoulder. Id. He opined petitioner had no prior injury or chronic condition that could explain his symptoms, and there was no other contemporaneous injury other than vaccination to explain his symptoms. Id.

B. Petitioner's Expert, Dr. Tony M. Korman

1. Background and Qualifications

Dr. Korman is the Director of Infectious Diseases and Director of Microbiology at Monash Health as well as an Adjunct Clinical Professor and Microbiologist at Monash University in Australia. Pet. Ex. 33 at 2; Pet. Ex. 34 at 1. He received his Bachelor of Medicine in 1988, then completed an internship, residency, and multiple fellowships from 1989 to 1997. Pet. Ex. 34 at 3. He has authored or co-authored numerous publications, participates as a reviewer for multiple journals, and is a member of various committees and societies. Id. at 4-40, 47, 53-54.

2. Opinion

Dr. Korman opined that petitioner, more likely than not, developed subacromial bursitis and impingement syndrome as a direct result of, and within 12 hours of, his flu vaccination. Pet. Ex. 33 at 4-5.

Like Dr. Boyd, Dr. Korman cited to Atanasoff et al. for support of the proposed mechanism of injury in SIRVA cases. Pet. Ex. 33 at 2-3. He explained the mechanism is “the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction.” Id. (quoting Pet. Ex. 15 at 1). Dr. Korman added that “[a] robust and prolonged reaction may be the response of a sensitised population who have had antigenic exposure from previous vaccination or previous infection.” Id. at 4. An “[u]nintentional injection into the synovial bursa or the glenohumeral joint can induce an intense immune and inflammatory response in the shoulder capsule and bursitis.” Id.

Dr. Korman also discussed how SIRVA can be associated with vaccine administration technique. Pet. Ex. 33 at 4. For example, vaccines have been reported to have been administered “very high” in the arm, between 1 and 3 cm from the acromion. Id. Dr. Korman cited to Bodor and Montalvo¹⁹ as evidence that vaccines have been “unintentionally delivered into the subdeltoid bursa or glenohumeral joint space because of its proximity to the deltoid muscle.” Id. In Bodor and Montalvo, the authors examined two patients with shoulder pain and weakness following vaccination and hypothesized that the “vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response.” Pet. Ex. 18 at 1-2. They explained, “[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule,” as well as “adhesive capsulitis.” Id. at 2. Because multiple structures within the shoulder were involved in both patients, Bodor and Montalvo found this suggested “a primary inflammatory etiology rather than a mechanical overuse problem.” Id. at 3. The authors concluded that “the diagnosis of vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection.” Id.

¹⁹ Marko Bodor & Enoch Montalvo, Vaccination-Related Shoulder Dysfunction, 25 Vaccine 585 (2007).

With regard to petitioner's shoulder injury, Dr Korman opined petitioner had no prior history of shoulder pain or limitations with range of motion. Pet. Ex. 33 at 4. Dr. Korman found petitioner's shoulder MRI showing subacromial bursitis or impingement syndrome was consistent with a SIRVA. Id. He found petitioner's complaints of shoulder pain when reaching overhead to be associated with the injury suffered by petitioner. Id. at 5. Additionally, although petitioner had some improvement in his pain after a corticosteroid injection in April 2016, he continued to experience limited range of motion through August 2016. Id. Dr. Korman concluded that petitioner continues to suffer from his shoulder injury. Id. at 6.

Additionally, Dr. Korman opined there was no other condition to explain petitioner's pain and loss of range of motion. Pet. Ex. 33 at 4. Although there is an entry from Dr. Thacker stating petitioner reinjured his shoulder after hanging drywall, Dr. Korman noted that petitioner testified that he had not hung drywall for 20 years. Id. at 5. Assuming Dr. Thacker's record is accurate, he found Dr. Thacker determined this was a "re-injury" to the SIRVA injury. Id. Thus, he opined it was "reasonable to conclude that this 're-injury' would not have occurred were it not for the earlier vaccination and the resultant shoulder injury, which could have been aggravated by rigorous use, and activities like hanging drywall certainly comport with that description." Id.

Dr. Korman also opined that petitioner suffered a typical SIRVA, where a previously asymptomatic shoulder condition is aggravated by an injection of a flu vaccine into the bursa, which was accompanied by secondary neurologic symptoms due to the effect and possible additional trauma to axillary nerve. Pet. Ex. 33 at 5. He found petitioner's injury was not neurologic, "even if there were second-order neurologic symptoms that arose after the shoulder was injured by the vaccination." Id. Dr. Korman found "[p]ain or numbness in the neck and hand on the side where [petitioner's] vaccination was administered is readily attributable to direct injury to the axillary nerve and/or as a secondary effect from the immobilization and guarding of the arm after the injury first occurred." Id. Thus, he concluded that "[r]egardless of the precise etiology of [petitioner's] neurologic symptoms," petitioner's symptoms and clinical course are consistent with a SIRVA. Id.

He cited medical literature to support the proposition that direct nerve injuries can occur due to needle trauma. Pet. Ex. 33 at 5. For example, Cook²⁰ developed an evidence-based protocol for safe vaccine administration into the deltoid muscle "by making anthropometric measurements of the surface anatomical landmarks" in 536 adults and "mapping the position of structures potentially injured by vaccine administration in relation to these landmarks." Pet. Ex. 24 at 1, 3. Cook found injections administered in certain locations "have the potential to cause injury to the subdeltoid/subacromial bursa and/or the anterior branch of the axillary nerve with the arm in the neutral position." Id. at 4. Cook also determined the radial nerve can be compromised when vaccines are administered outside the recommended area. Id.

Dr. Korman found the short onset interval between vaccination and pain, along with the lack of an alternative etiology, to be "convincing evidence linking [petitioner's] shoulder pain associated with subacromial bursitis and vaccine administration." Pet. Ex. 33 at 5. Thus, for all

²⁰ Ian F. Cook, An Evidence Based Protocol for the Prevention of Upper Arm Injury Related to Vaccine Administration (UAIRVA), 7 Human Vaccines 845 (2011).

the reasons stated above, Dr. Korman concluded that more likely than not, petitioner's flu vaccination caused his shoulder injury. Id. at 4-5.

C. Respondent's Expert, Dr. Paul J. Cagle

1. Background and Qualifications

Dr. Cagle is a board-certified orthopaedic surgeon. Resp. Ex. A at 1. He currently works as an Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Id. He received his B.S. in Biology from St. Ambrose University in 2004 and his M.D. from Loyola University in 2008. Resp. Ex. B at 2. Thereafter, he completed an orthopaedic surgery residency at the University of Minnesota, a shoulder and elbow fellowship at Mount Sinai Hospital, and a shoulder fellowship in France. Id. Dr. Cagle has received various honors, has co-authored various publications, and held multiple leadership and professional membership positions throughout his career. Id. at 2-3, 11-14.

2. Opinion

Dr. Cagle opined that petitioner's bursitis, shoulder pain and range of motion, neck pain, back pain, and cervical spine and neck pain are not correlated with or caused by the flu vaccination at issue. Resp. Ex. A at 4. Dr. Cagle based his opinion on three reasons:²¹ (1) no information regarding needle size or technique were provided and it is not conceivable that a standard needle would have over penetrated petitioner's deltoid muscle; (2) petitioner's preexisting conditions can explain petitioner's symptoms; and (3) petitioner's MRI findings do not support a SIRVA. Id. at 3-4.

First, Dr. Cagle found the most common mechanism associated with SIRVA is "over penetration of the vaccination injection needle causing a mechanical injury and/or over penetration leading to the injection of the vaccine antigen/adjuvant into the bursa/tissue causing an immune reaction." Resp. Ex. A at 3. For this to occur, he opined that a long needle or inappropriate technique must have been used. Id.

Dr. Cagle noted that in petitioner's case, no information regarding needle size or technique were provided. Id. Assuming the needle used on petitioner was the standard needle length of one inch, he opined that "it is not conceivable how a standard needle would have led to an over penetration event" based on the medical literature and petitioner's weight on the date of vaccination (220 lbs or 100 kg). Id. Dr. Cagle explained that the "Centers for Disease Control and Prevention guidelines recommend a 1-inch (25mm) needle length for all patients except women over 200 [lbs], males over 260 lbs (113 kg)[,] and newborns." Id.

²¹ Dr. Cagle also opined there is no evidence associating vaccination with the onset of petitioner's shoulder injury within 48 hours. Resp. Ex. A at 3. However, because the undersigned previously issued a ruling finding petitioner's onset was within 48 hours of vaccination, this issue is not addressed in this Ruling.

Dr. Cagle also cited to Poland et al.²² and Koster et al.²³ to support his proposition that a needle over one inch would be necessary to penetrate the bursa. Resp. Ex. A at 3. In Poland et al., the authors conducted a study of 220 people, 126 women and 94 men, to determine the optimal needle length for deltoid intramuscular immunization in healthy adults. Resp. Ex. A, Tab 27 at 1. They found a one-inch needle sufficient to allow at least 5 mm of muscle penetration in men between 60-118 kg. Id. at 3. Koster et al. examined 141 subjects between the ages of 11 and 15, 55% being female, to determine appropriate needle length for intramuscular injection. Resp. Ex. A, Tab 28 at 1. They found a one-inch needle appropriate for subjects between 60 and 70kg. Id. at 4. They also determined that “body weight is an excellent predictor of required needle length.” Id. Notably, this study examined adolescents, and not adults. Id. at 1. And because only seven subjects weighed more than 70 kg, the authors made no recommendations for this group. Id. at 4.

Next, Dr. Cagle opined that petitioner had a “long standing and well documented history” of joint and back pain that could explain petitioner’s pain. Resp. Ex. A at 3-4. Dr. Cagle cited to medical records from Dr. Patel and Dr. Thacker as support. Id. He noted Dr. Patel’s diagnosis of peripheral neuropathy “clearly explain[s] why [petitioner] was having numbness in his hand as documented during his visits with [Dr. Thacker].” Id. at 3. Additionally, Dr. Thacker documented a long standing history of cervical pain,²⁴ which Dr. Cagle opined is an “additional and common reason for hand numbness” and “demonstrates a self-reported history of episodic pain . . . off and on for year” that is associated with petitioner’s strenuous job. Id. at 4. Thus, Dr. Cagle opined that given petitioner’s “long standing episodic history of joint and back pain,” he disagreed with Dr. Korman that no other explanation exists to explain petitioner’s symptoms. Id. He added that Dr. Korman did not explain how petitioner’s numbness that Dr. Korman associated with the bursitis is different than petitioner’s years of documented numbness. Id.

Lastly, Dr. Cagle opined that petitioner’s MRI findings do not support a finding of SIRVA. Resp. Ex. A at 4. The MRI showed a downsloping acromion, which has been found to cause bursitis and impingement syndrome. Id. Thus, he found petitioner was predisposed to shoulder bursitis and impingement syndrome due to his “bony morphology” and “occupational history of heavy work.” Id. Dr. Cagle concluded that the combination of petitioner’s bony morphology and occupational work explains the etiology of petitioner’s shoulder issues. Id.

²² Gregory A. Poland et al., Determination of Deltoid Fat Pad Thickness: Implications for Needle Length in Adult Immunization, 277 JAMA 1709 (1997).

²³ Michael Philip Koster et al., Needle Length for Immunization of Early Adolescents as Determined by Ultrasound, 124 Pediatrics 667 (2009).

²⁴ Dr. Thacker’s record does not document a long standing history of cervical pain. See Pet. Ex. 5 at 3. Dr. Thacker documented, “[petitioner] has suffered from upper thoracic pain for many years. [Petitioner] explain[ed] that he has worked throughout his life in strenuous job setting that have placed above normal amounts of tension stress to upper thoracic spine.” Id.

Dr. Cagle concluded that petitioner's flu vaccination did not cause petitioner's symptoms. Resp. Ex. A at 4. He found petitioner's medical records documented his history of joint pain and his MRI supports a finding that petitioner was predisposed to bursitis due to the shape of his shoulder and occupation. Id.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that he suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner’s claim predates the inclusion of SIRVA on the Table, he must prove his claim by showing that his injury was caused-in-fact by the vaccination in question. § 11(c)(1)(C)(ii). To do so, petitioner must establish, by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The undersigned must

weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The mechanism for a SIRVA injury is well described in the medical literature filed in this case. In Atanasoff, the authors propose that the causal mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Pet. Ex. 15 at 1. They found "rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. MRI findings supported the conclusion that shoulder impairments, such as rotator cuff tears, "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. Similarly, Bodor and Montalvo proposed that a "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet. Ex. 18 at 1-2. They found multiple structures within the shoulder involved, which suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3.

Further, when proposing the addition of SIRVA to the Vaccine Table, respondent discussed the mechanism by which this injury is caused. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015).

The undersigned takes judicial notice of the fact that respondent has added SIRVA after receipt of an intramuscularly administered flu vaccine to the Table. Such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first Althen prong. See Doe 21 v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 178, 193 (2009), rev’d on other grounds, 527 F. App’x. 875 (Fed. Cir. 2013).

Moreover, petitioner submitted the expert opinions of Drs. Boyd and Korman who provided a sound and reliable medical and scientific theory of causation supported by medical literature. In summary, Dr. Korman explained that the “injection of antigenic material into synovial tissues [can result] in an immune-mediated inflammatory reaction,” leading to “[a] robust and prolonged reaction” and the development of subacromial bursitis and impingement syndrome. Pet. Ex. 33 at 3-4.

For all of the above reasons, the undersigned finds petitioner has provided by preponderant evidence a sound and reliable theory that the flu vaccine administered intramuscularly can cause SIRVA, and therefore, petitioner has satisfied the first Althen prong.

B. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is a preponderance of evidence in the record to support a logical sequence of cause and effect showing the November 11, 2015 flu vaccination to be the cause of petitioner’s right shoulder pain. See Althen, 418 F.3d at 1278.

Petitioner received the flu vaccine at issue on November 11, 2015. The first time he was seen by a medical doctor was on February 29, 2016, at Dr. Patel’s office. While earlier records reference neck pain, the focus soon became petitioner’s right shoulder pain. A shoulder MRI

was ordered, and performed on March 1, 2016. The MRI of petitioner's right shoulder showed "[s]omewhat inferiorly projecting acromion process with mild increased signal intensity changes in the subacromial bursa [that] could represent impingement syndrome or [] bursitis." Pet. Ex. 3 at 2. Dr. Thacker's records continued to document decreased range of motion in March and April 2016. Pet. Ex. 5 at 24, 48.

Dr. Patel's office, on April 11, 2016, documented right shoulder tenderness with marked restricted movements and normal range of motion. Pet. Ex. 4 at 38. Assessment included "right shoulder pain etiology to be determined." Id. at 39. Additional visits to Dr. Patel in 2016 and 2017 revealed normal range of motion on physical examination. Pet. Ex. 7 at 2, 4, 6; Pet. Ex. 9 at 1, 3-4. For each of these visits, however, petitioner presented to Dr. Patel for issues other than his right shoulder pain. It is reasonable that petitioner would not discuss his right shoulder pain during these visits when he presented for other reasons and was also seeing Dr. Thacker during most of 2016 for his shoulder issues.

On April 18, 2016, petitioner saw orthopedist Dr. Jamie Varney. Pet. Ex. 2 at 3, 7. Physical examination revealed positive signs on Hawkins and Neer's tests and the cross body test for shoulder joint pathology. Id. at 5. "[P]ain in impingement arc" was noted in petitioner's right shoulder. Id. at 6. Upper extremity strength was normal except for "mild decreased right supraspinatus due to pain." Id. Assessment was impingement syndrome and bursitis of right shoulder. Id.

Based on a review of all of the records in context, while petitioner's treating physicians may have initially documented concerns with the neck or cervical spine, they soon thereafter focused on his right shoulder as the primary problem. Dr. Patel initially considered degenerative disease of cervical spine; however, it does not appear he ever ordered a cervical spine MRI. The medical records do not include any such study, and only an MRI of petitioner's right shoulder was performed. Additionally, Dr. Thacker's records show his primary concern was petitioner's right shoulder pain and pathology, not the cervical spine. Likewise, Dr. Varney's records focus on petitioner's shoulder.

Thus, based on all of the evidence, the undersigned finds petitioner developed a SIRVA, specifically impingement syndrome and bursitis, consistent with Dr. Varney's assessment. This finding is also consistent with the evidence presented by petitioner and his experts.

Respondent's expert, Dr. Cagle opined that petitioner had a "long standing and well documented history" of joint and back pain that could explain petitioner's pain. Resp. Ex. A at 3-4. He found Dr. Patel's diagnosis of peripheral neuropathy explains petitioner's hand numbness. Id. at 3. Additionally, he found Dr. Thacker's documentation of a long standing history of cervical pain an "additional and common reason for hand numbness." Id. at 4. However, Dr. Thacker's record does not document a long standing history of cervical pain. See Pet. Ex. 5 at 3. Instead, Dr. Thacker documented, "[petitioner] has suffered from upper thoracic pain for many years. [Petitioner] explain[ed] that he has worked throughout his life in strenuous job setting that have placed above normal amounts of tension stress to upper thoracic spine." Id.

Dr. Cagle also opined petitioner was predisposed to shoulder bursitis and impingement syndrome due to his “bony morphology” and “occupational history of heavy work.” Resp. Ex. A at 4. Thus, he attributed petitioner’s shoulder issues to his bone structure and work history. Id.

Petitioner’s experts disagreed. Dr. Boyd found no evidence to support a neurologic etiology and no evidence of another condition to explain petitioner’s pain or loss of range of motion in his shoulder. Pet. Ex. 13 at 8. He opined petitioner had no prior injury or chronic condition that could explain his shoulder symptoms, and there was no other contemporaneous injury other than vaccination to explain his symptoms. Id.

Likewise, Dr. Korman found no other condition to explain petitioner’s shoulder pain and loss of range of motion. Pet. Ex. 33 at 4. He opined petitioner’s complaints of numbness were more likely than not a result of his SIRVA. Id. at 5. He found petitioner’s injury was not neurologic, “even if there were second-order neurologic symptoms that arose after the shoulder was injured by the vaccination.” Id. The “[p]ain or numbness in the neck and hand on the side where [petitioner’s] vaccination was administered is readily attributable to direct injury to the axillary nerve and/or as a secondary effect from the immobilization and guarding of the arm after the injury first occurred.” Id. And therefore, “[r]egardless of the precise etiology of [petitioner’s] neurologic symptoms,” petitioner’s symptoms and clinical course are consistent with a SIRVA. Id.

The undersigned acknowledges that petitioner had a history of back and joint pain, diabetic neuropathy, and a labor-intensive job. However, Atanasoff et al. stated that in many cases, conditions including “impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis[,] and adhesive capsulitis[,] . . . may cause no symptoms until provoked by trauma or other events.” Pet. Ex. 15 at 3. The authors concluded that “some of the MRI findings . . . may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.” Id. Here, petitioner may have had pre-existing pathology, but he was not symptomatic until after vaccination.

While petitioner’s job and pre-vaccination history may have made it more likely for him to have suffered a shoulder injury, the undersigned finds that it was not an alternative cause, or factor unrelated to vaccination, which caused petitioner’s symptoms. As Dr. Boyd explained, petitioner’s shoulder symptoms began only after vaccination, which is further supported by Atanasoff et al. Thus, the undersigned finds petitioner’s vaccination was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

In conclusion, the undersigned finds petitioner has proven by preponderant evidence a logical sequence of cause and effect and has satisfied the second Althen prong.

C. Althen Prong Three

Althen Prong Three requires petitioner to establish a “proximate temporal relationship” between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a “medically acceptable temporal relationship.” Id. The petitioner must offer

“preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec’y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013).

As stated above, the undersigned found the onset of petitioner’s right shoulder pain occurred within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. See Althen, 418 F.3d at 1278.

The undersigned finds the evidence discussed in the prior Fact Ruling establishes that the flu vaccine caused petitioner’s shoulder injury within the time frame required. The temporal association is appropriate given the mechanism of injury. Thus, petitioner has satisfied the third Althen prong.

D. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence “that [petitioner’s] injury was in fact caused by factors unrelated to the vaccine.” Whitecotton v. Sec’y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev’d on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec’y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen Prong Two, the undersigned found the respondent failed to establish evidence to show that petitioner’s SIRVA injury was caused by a source other than his vaccination. Thus, respondent did not prove by a preponderance of evidence that petitioner’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B).

VI. CONCLUSION

Based on the record as a whole and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish petitioner’s November 11, 2015 flu vaccination caused his right shoulder injury. Thus, the undersigned finds that petitioner has established by preponderant evidence that he is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master